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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,643	10/05/2000	Timothy Jmaes Foster	P0628US02/BAS	8447
881	7590	11/16/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			GRASER, JENNIFER E	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/679,643

Applicant(s)

FOSTER ET AL.

Examiner

Jennifer E. Graser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/19/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Acknowledgment and entry of the Preliminary Amendment submitted on 10/5/00 is made. Claims 1-7 are pending and under examination.

Specification

1. The current status of all nonprovisional parent applications referenced on page 1 of the specification should be updated, e.g., 09/421,868 is a U.S. Patent now.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6 and 7 are vague and indefinite due to the phrase "raised against". The phrase should be changed to "specifically binds" in order to more clearly convey the immunogenic properties of the antibody. The phrase "raised against" does not necessarily indicate that the antibody would have the ability to specifically bind the protein encoded by SEQ ID NO:1.

Claims 1 and 7 are also vague and indefinite due to the phrase "produced by a microorganism expressing a DNA molecule consisting of SEQ ID No. 1 or degenerates thereof". This phrase does not convey that the microorganism is a transformed host cell, nor does it clearly convey that SEQ ID NO:1 is the sequence which encodes the fibrinogen binding protein. The claim should recite that the antibody/antisera specifically

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binds an *S.aureus* fibrinogen protein consisting of SEQ ID NO:2, or that the antibody/antisera specifically binds an *S.aureus* fibrinogen protein which is encoded by a nucleic acid sequence consisting of SEQ ID NO:1. The claim only needs to recite that the antibody binds the protein encoded by SEQ ID NO:1 and does not need to limit the scope to only recombinant proteins, e.g., antibodies to proteins produced by a microorganism consisting of SEQ ID NO:1.

Claims 4 and 5 are vague and indefinite due to the phrase "raised against". The phrase should be changed to "specifically binds" in order to more clearly convey the immunogenic properties of the antibody. The phrase "raised against" does not necessarily indicate that the antibody would have the ability to specifically bind the protein expressed by the deposited microorganism.

Claims 4 and 5 are vague and indefinite because the wording is confusing. What is deposited, the plasmid or the transformed microorganism? Do applicants intend to claim an isolated antibody which specifically binds the protein expressed by the plasmid deposited with the NCIMB? Claims 4 and 5 do not convey that the microorganism is a transformed host. It is suggested that the claim be amended to recite "an isolated antibody which specifically binds an *S.aureus* fibrinogen binding protein which is expressed by a microorganism which has been transformed with plasmid pCF3[10], Accession No. 40959[40674], which is deposited at the NCIMB.". The current wording of the claim is vague and confusing.

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Claims 4 and 5 are vague and indefinite due to the phrase "degenerates thereof".

It is unclear how there can be a degenerate of a plasmid or a microorganism.

Clarification and correction is requested.

It appears in claim 6 that Applicants intend to claim antibodies which specifically bind particular portions of the fibrinogen binding protein. However, the use of the open term "comprising" in line 1 of the claims allows for antibodies which bind anywhere along the full-length sequence. If Applicants intend to claim antibodies which specifically bind an epitope within the recited amino acid ranges, then the word 'comprising' should be changed to 'consisting of'.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of plasmid pCF10 or pCF3. Because it is not clear that the properties of plasmids pCF10 or pCF3 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification

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requires the use of the plasmids, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production plasmids, one of ordinary skill in the art could be assured to the ability to practice the invention as claimed. Exact replication of the plasmids is an unpredictable event.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1)The name and address of the depository;
- 2)The name and address of the depositor;
- 3)The date of deposit;
- 4)The identity of the deposit and the accession number given by the depository;
- 5)The date of the viability test;

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6)The procedures used to obtain a sample if the test is not done by the depository; and

7)A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by McDevitt et al (Molec. Microbiol., January 1994, 11(2): 237-248).

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McDevitt et al teach an isolated *S.aureus* fibrinogen protein which is encoded by a nucleic acid sequence which is identical to Applicants' SEQ ID NO:1. The protein has an amino acid sequence which is identical to SEQ ID NO:2. McDevitt et al teach isolated antibodies and antisera raised against this protein. The proteins expressed by plasmids pCF3 and pCF10 is identical to that which is encoded by SEQ ID NO:1 and degenerates thereof. Therefore, an isolated antibody raised against a protein produced by a microorganism transformed with either plasmid would be identical to the antibody taught by McDevitt et al. Claim 6 uses the open term "comprising" therefore it encompasses antibodies which bind anywhere along the full-length sequence.

The inventive entity of the reference differs from that of the present application.

Applicants may file a Declaration to overcome the reference.

Information Disclosure Statement

8. The information submitted on the PTO 892 which accompanied the IDS of 1/19/01 is not in proper format. If Applicants wish for the references to be considered they must comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The references must be submitted on a PTO-1449 form. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all

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certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609

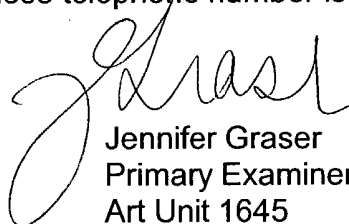
¶ C(1).

9. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645
11/10/07